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(54) Title: WORLDWIDE PATIENT LOCATION AND DATA TELEMETRY SYSTEM FOR IMPLANTABLE MEDICAL DEVICES				
(57) Abstract <p>A system for communicating with a medical device (10) implanted in an ambulatory patient and for locating the patient in order to selectively monitor device function, alter device operating parameters and modes and provide emergency assistance to and communications with a patient (10). The implanted device (10) includes a telemetry transceiver for communicating data and operating instructions between the implanted device and an external patient communications control device (20) that is either worn by or located in proximity of the patient within the implanted device transceiving range. The control device preferably includes a communication link with a remote medical support network (50), a global positioning satellite (80) receiver for receiving positioning data identifying the global position of the control device, and a patient activated link for permitting patient initiated personal communication with the medical support network (50). A system controller (24) in the control device (20) controls data and voice communications for selectively transmitting patient initiated personal communications and global positioning data to the medical support network (50), and for receiving and initiating re-programming of the implanted device operating modes and parameters in response to instructions received from the medical support network (50). The communications link between the medical support network and the patient communications control device may comprise a worldwide satellite network, hard-wired telephone network, a cellular telephone network (82) or other personal communications system.</p>				

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WORLD WIDE PATIENT LOCATION AND DATA TELEMETRY
SYSTEM FOR IMPLANTABLE MEDICAL DEVICES

FIELD OF THE INVENTION

5 The present invention relates to communication systems for communicating with an implanted medical device or device system, and more particularly, such a communication system that may function on a world wide basis at any time to communicate patient location, device monitoring data, device re-programming data and to allow for effective response to emergency conditions.

10 The following references were cited in commonly assigned, co-pending U.S. Patent Application Serial No. 08/584,851 for ADAPTIVE, PERFORMANCE-OPTIMIZING COMMUNICATION SYSTEM by S. Goedeke et al. to indicate the prior state of the art in such matters. In particular, in reed switch use U.S. Patent No. 3,311,111 to Bowers, U.S. Patent No, 3,518,997 to Sessions, U.S. Patent No. 3,623,486 to Berkovits, U.S. Patent No, 3,631,860 to Lopin, U.S. Patent No., 3,738,369 to Adams et al., U.S. Patent No. 3,805,796 to Terry, Jr., U.S. Patent No. 4,066,086 to Alferness et al.; informational type U.S. Patent 4,374,382 to Markowitz, U.S. Patent No, 4,601,291 to Boute et al.; and system U.S. Patent No. 4,539,992 to Calfee et al., U.S. Patent No. 4,550,732 to Batty Jr., et al., U.S. Patent No, 4,571,589 to Slocum et al., U.S. Patent No. 4,676,248 to Berntson, U.S. Patent No. 5,127,404 to Wyborny et al., U.S. Patent No. 4,211,235 to Keller, Jr. et al., U.S. patents to Hartlaub et al., U.S. Patent No. 4,250,884, U.S. Patent No. 4,273,132, U.S. Patent No. 4,273,133, U.S. Patent No. 4,233,985, U.S. Patent No. 4,253,466, U.S. Patent No. 4,401,120, U.S. Patent No. 4,208,008, U.S. Patent No. 4,236,524, U.S. Patent No. 4,223,679 to Schulman et al., U.S. Patent No. 4,542,532 to McQuilkin, and U.S. Patent No. 4,531,523 to Anderson.

BACKGROUND OF THE INVENTION

Over the years, many implantable devices have been developed to monitor medical conditions and deliver therapy to a patient. Such devices included electrical stimulation devices for stimulating body organs and tissue to evoke a response for enhancing a body function or to control pain, and drug delivery devices for releasing a

drug bolus at a selected site. Other more passive implantable and wearable medical devices have been developed for monitoring a patient's condition.

Chronically implanted cardiovascular devices for monitoring cardiovascular conditions and providing therapies for treating cardiac arrhythmias have vastly improved patients quality of life as well as reduced mortality in patients susceptible to sudden death due to intractable, life threatening tachyarrhythmias. As implanted device technology has grown more sophisticated with capabilities to discover, monitor and affect more patient conditions (including otherwise life threatening conditions) patients have enjoyed freedom from hospital or home confinement or bed rest.

However, the improved mobility brings with it the need to maintain communications with the patient and the implanted device.

Early in the development of cardiac pacemakers, patient follow-up to monitor pacemaker operation was facilitated by telephonic transmissions of skin surface ECGs in real time to a physician's office employing such systems as the MEDTRONIC® TeleTrace® ECG transmitter. Over time, various patient worn, ambulatory ECG and device monitors have been developed for providing ECG data for remote analysis of cardiac arrhythmias. Also, the remotely programmable modes of operation of implantable medical devices increased, and programming methods improved.

In current arrhythmia control devices, (e.g. cardiac pacemakers, and pacemaker cardioverter-defibrillators) a relatively wide range of device operating modes and parameters are remotely programmable to condition the device to diagnose one or more cardiac arrhythmia and deliver an appropriate therapy. In cardiac pacemakers, the pacing rate in one or both heart chambers is governed by algorithms that process the underlying cardiac rhythm as well as physiologic conditions, e.g. patient activity level and other measured variables, to arrive at a suitable pacing rate. The pacemaker operating modes and the algorithm for calculation of the appropriate pacing rate are programmed or reprogrammed into internal memory by accessing the implanted pacemaker's telemetry transceiver with an external programmer. Even the diagnosis of a tachyarrhythmia requiring delivery of a treatment therapy and the therapies to be delivered may now be governed by operating modes and algorithm parameters that can be programmed into and changed using such a programmer.

Such implanted devices can also process the patient's electrogram and any measured physiological conditions employed in the diagnosis and store the data, for subsequent telemetry out on interrogation by the external programmer. The telemetered out data is analyzed and may be employed to establish or refine the operating modes and parameters by a doctor to adjust the therapies the device can deliver. In general, the manner of communicating between the transceivers of the external programmer and the implanted device during programming and interrogating is referred to as telemetry.

Initially, when programming techniques were first devised, the paramount concern addressed related to patient safety. Safeguards addressed the concern that the patient could be put at risk of inadvertent mis-programming of the implanted device, e.g. by stray electromagnetic fields. For this reason, and in order to avoid high current consumption that would shorten the implanted device battery life, telemetry operating range was extremely limited. In systems continuing to the present time, telemetry has required application of a magnetic field at the patient's skin over the implanted device to close a reed switch while RF programming or interrogating commands are generated to be received by the implanted device transceiver. The programming or interrogating commands are decoded and stored in memory or used to trigger telemetry out of stored data and operating modes and parameters by the implanted device transceiver.

As stated at the outset, one of the rationales and attributes of implanted medical devices of the type described, is that the patient is allowed to be ambulatory while his medical condition is monitored and/or treated by the implanted medical device. As a further safety precaution, "programmers" (devices capable of programming all the operating modes or functions of the implanted device and for initiating interrogation through the telemetry system) are generally not provided to the patients. Patients are periodically examined and device interrogation is conducted by the physician using the external "programmer" during follow-up visits to the physicians office or clinic. This limits the frequency of monitoring and may require certain patients to remain close to the physician's office.

Emergency conditions (device failure, physiologic variable changes resulting in inappropriate therapy, transient conditions/problems) may require additional monitoring or follow-up.

The short range of conventional device telemetry is itself viewed as unduly limiting of a patient's mobility. In the medical monitoring field, longer range, continuously accessible telemetry has been sought and systems for doing so have been proposed. In U.S. Patent No. 5,113,869 for example, an implanted ambulatory ECG patient monitor is described that is provided with longer range telemetry communication with a variety of external accessory devices to telemeter out alarm signals and ECG data and to receive programming signals. The high frequency RF signals are encoded, including the implanted device serial number, to ensure that the communication is realized only with the proper implanted device and that it is not mis-programmed.

Telemetry communication with other implanted devices, particularly drug infusion pumps or pacemaker-cardioverter-defibrillator devices, to initiate or control their operation is also disclosed. Communication between the implanted AECG monitor and an external defibrillator is also suggested through low current pulses transmitted from the defibrillator paddles through the body link in order to condition the implanted AECG monitor to provide telemetry signals to the external defibrillator.

One of the external devices disclosed in the '869 patent is a wrist worn, personal communicator alarm for responding to a telemetered out signal and emitting a warning to the patient when the implanted AECG monitor has detected an arrhythmia. The patient is thereby advised to take medications or contact the physician or to initiate external cardioversion. The personal communicator alarm also includes a transceiver and may also be used to control certain functions of the implanted AECG monitor. A further, belt worn "full disclosure recorder" is disclosed with high capacity memory for receiving and storing data telemetered out of the implanted AECG monitor when its memory capacity is exhausted.

A remote, external programmer and analyzer as well as a remote telephonic communicator are also described that may be used in addition to or alternately to the personal communicator alarm and/or the full disclosure recorder. The programmer

and analyzer may operate at a distance to the implanted AECG monitor to perform programming and interrogation functions. Apparently, the implanted AECG may automatically transmit a beacon signal to the programmer and analyzer to initiate an interrogation function to transmit data to the programmer and analyzer on detection of an arrhythmia or a malfunction of the implanted AECG monitor detected in a self-diagnostic test. Or by setting a timer in the personal communicator alarm, the implanted AECG monitor may be automatically interrogated at preset times of day to telemeter out accumulated data to the telephonic communicator or the full disclosure recorder. The remote telephonic communicator may be part of the external programmer and analyzer and is automatically triggered by the alarm or data transmission from the implanted AECG monitor to establish a telephonic communication link and transmit the accumulated data or alarm and associated data to a previously designated clinic or physician's office through a modem.

The combination of external devices provided to a given patient is at the discretion of the physician. It is preferred that at least the patient be provided with the external programmer and analyzer including a communications link.

A similar programmer/interrogator for an implanted pacemaker-cardioverter-defibrillator device is disclosed in U.S. Patent No. 5,336,245, wherein the data accumulated in the limited capacity memory implanted device is telemetered out to a larger capacity, external data recorder. The accumulated data is also forwarded to a clinic employing an auto-dialer and FAX modem resident in a personal computer-based, programmer/interrogator.

In each of these disclosed systems, presumably, the patient is able to communicate with the physician's office or clinic contemporaneously with the transmission of data by modem. In all such telemetry systems for programming an operating mode or parameter or interrogating accumulated patient data or device operating modes and parameters, the patient is located within a short range, typically within sight, of the remote devices, particularly the remote programmer. If the patient is out of range of the programmer and an attached telephone system, the security of the patient is diminished. Consequently, at risk patients are advised to remain close by to the programmer and telephone for their safety.

Figure 2 is a schematic illustration of the system of Figure 1 in relation to a patient;

Figure 3 is block level diagram of a second variation of the system of the invention for a patient having limited mobility including an implantable medical device, a patient communications control device and a medical support network employing conventional wired telecommunication;

Figure 4 is a schematic illustration of the system of Figure 3 in a line powered monitor for use in a patient's hospital room;

Figure 5 is a schematic illustration of the system of Figure 3 employing a patient-worn, communications link and a line powered monitor for use in a patient's home; and

Figure 6 is a block diagram of an exemplary implanted medical device with which the invention may be practiced.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The Global Communications and Monitoring System (GCMS) of the present invention provides a means for exchanging information with and exercising control over one or more medical devices implanted within the body of a patient employing the patient communications control device. The GCMS in its most comprehensive form of Figures 1 and 2 is intended to function no matter how geographically remote the patient may be relative to the monitoring site or medical support network. In this form, the GCMS provides an alarm to notify the medical support network should device or patient problems arise, determines patient location via the Geopositioning Satellite System (GSS), and allows verbal communication between the patient and monitoring personnel via a cellular telephone system link (if available at the patient location) or a satellite based telecommunications link if the patient is outside the range of a cellular link or subscribes only to the satellite-based link.

The system is not intended to be limited to such remote use by a free ranging patient and is intended to also be used when the patient is less mobile. In the subsystem or second variation illustrated in Figures 3-5, the patient communication control device is intended to be coupled to a telephone or other communications system for a patient with more limited mobility. For example, the standard

telecommunications system may be accessed either through a hard-wired link or by a cordless telephone with a telephone receiver in the room attached to a phone jack. In this case, the cellular or satellite-based telecommunications interface capabilities are not necessary, and the GSS capability may be superfluous.

5 Preferably, the GCMS of Figure 1 includes all of these capabilities embodied in a patient communications control device that is small and light enough to be attached to the patient when the patient is mobile or to be used by the patient as a free standing unit at the patient's residence or hospital room. Alternatively, as shown in Figures 3-5, the GCMS can be re-configured in part as a stand alone, line powered, 10 room monitor and the remaining part can be implemented as a patient-worn, battery powered, communications link with a transceiver capable of two-way communication between the patient, the implanted medical device and the line powered monitor.

15 Figures 1 and 3 are intended to show the alternate components of both of the variations of the GCMS, although the alternate components may be included in the same GCMS. The patient 10 has one or more implanted medical devices 12, 14, which in the latter case may communicate with one another is known as, for example, using the body medium in a manner described in commonly assigned U.S. Patent No. 4,987,897 to Funke. The medical device 12 (and associated device 14, if present) may be, for example, an arrhythmia control device, e.g. a cardiac pacemaker or a 20 pacemaker-cardioverter-defibrillator. A relatively wide range of device operating modes and parameters are remotely programmable to condition such a device 12 to diagnose one or more conditions such as cardiac arrhythmias and/or deliver electrical or other stimulus appropriate for therapy. The implanted medical device 12 may alternatively be a drug administration device, cardiomyoplasty device, neural 25 stimulator or any other implantable device with electronic control functions that can be programmed and/or have memory for storing patient and device operating data.

At least one implanted medical device 12 possesses a transceiver of the type known in the art for providing two-way communication with an external programmer. The encoded communication may be by the RF transmission system such as is 30 described in the above-referenced '869 patent or by using spread spectrum telemetry techniques described in U.S. Patent No. 5,381,798 to Burrows or by the system

disclosed in the above-referenced U.S. Application Serial No. 08/584,851 or any of the known substitutes. The telemetry technique employed and the transceiver of the implanted medical device 12 have enough range to communicate between the transceiver in the implant wireless interface 22 in the remote patient communications control device 20 and the implant (12...14). The system disclosed in the above-referenced U.S. Application Serial No. 08/584,851 may be employed to increase the accuracy and efficiency of the uplink and downlink telemetry.

Figure 6, depicts an implantable pulse generator (IPG) circuit 300 and atrial and ventricular lead system 112, 114 having programmable modes and parameters and a telemetry transceiver of a DDDR type known in the pacing art as an example of an implanted medical device 12. While described in some detail, this device 12 provides only one example of the kind of implantable device that may be employed with this invention.

The IPG circuit 300 of Figure 6 is divided generally into a microcomputer circuit 302 and a pacing circuit 320. The pacing circuit 320 includes the output amplifier circuit 340 and the sense amplifiers 360. The output circuit 340 and sense amplifier circuit 360 may contain pulse generators and sense amplifiers corresponding to any of those presently employed in commercially marketed cardiac pacemakers for atrial and ventricular pacing and sensing. The bipolar leads 112 and 114 are illustrated schematically with their associated electrode sets 116 and 118, respectively, as coupled directly to the input/output circuit 320. However, in the actual implanted device they would, of course, be coupled by means of removable electrical connectors inserted in a connector block.

Sensed atrial depolarizations or P-waves that are confirmed by the atrial sense amplifier (ASE) in response to an A-sense are communicated to the digital controller/timer circuit 330 on ASE line 352. Similarly, ventricular depolarizations or R-waves that are confirmed by the ventricular sense amplifier in response to a V-sense are communicated to the digital controller/timer circuit 330 on VSE line 354.

In order to trigger generation of a ventricular pacing or VPE pulse, digital controller/timer circuit 330 generates a trigger signal on V-trig line 342. Similarly, in

order to trigger an atrial pacing or APE pulse, digital controller/timer circuit 330 generates a trigger pulse on A-trig line 344.

Crystal oscillator circuit 338 provides basic timing clock for the pacing circuit 320, while battery 318 provides power. Power-on-reset circuit 336 responds to initial connection of the circuit to the battery for defining an initial operating condition and may reset the operative state of the device in response to a low battery condition.

Reference mode circuit 326 generates stable voltage and current references for the analog circuits within the pacing circuit 320. Analog to digital converter (ADC) and multiplexor circuit 328 digitizes analog signals. When required the controller circuit will cause transceiver circuit 33 to provide real time telemetry if a cardiac signals from sense amplifiers 360. Of course, these circuits 326, 328, 336, and 338 may employ any circuitry similar to those presently used in current marketed implantable cardiac pacemakers.

Data transmission to and from the external programmer of the patient communications control device of the preferred embodiment of the invention is accomplished by means of the telemetry antenna 334 and an associated RF transmitter and receiver 322, which serves both to demodulate received downlink telemetry and to transmit uplink telemetry. Uplink telemetry capabilities will typically include the ability to transmit stored digital information, e.g. operating modes and parameters, EGM histograms, and other events, as well as real time EGMs of atrial and/or ventricular electrical activity and Marker Channel pulses indicating the occurrence of sensed and paced depolarizations in the atrium and ventricle, as is well known in the pacing art. The IPG transceiver system disclosed in the above-referenced U.S. Application Serial Number 08/584,851 may be employed to provide the uplink and downlink telemetry from and to the implanted medical device in the practice of the present invention.

Control of timing and other functions within the pacing circuit 320 is provided by digital controller/timer circuit 330 which includes a set of timers and associated logic circuits connected with the microcomputer 302. Microcomputer 302 controls the operational functions of digital controller/timer 324, specifying which timing intervals are employed, and controlling the duration of the various timing intervals,

implanted device need only be able to communicate with the cellular communications product.

Figure 2 illustrates the free ranging patient 10 located remotely from the medical support network 50 and from any hard-wired communications link. The patient communications control device 20 is implemented in the belt-worn portable unit 40, although the patient link 26 may be worn separately on the patient's wrist (not shown). Alternatively, the patient communications control device 20 including the patient link 26 may be packaged into a portable telephone configuration and carried in a pocket. In any embodiment, the patient location may be determined by communications with the GPS 62. The voice and data communications link with the medical support network 50 may be effected by a cellular phone link including transceiver 82. Alternatively, the voice and data communications link may be effected using the communications satellite link 80.

The patient communications control device 20 of Figures 1 and 2 is powered by a battery power supply 74 that preferably is rechargeable. The system controller 24 includes a power control system for powering down the microprocessor and the associated components of the patient communications control device 20 except on receipt of an interrupt in a manner well known in the art.

Power consumption can be significantly reduced by powering up the communication and satellite circuitry periodically for a short period of time to re-acquire a GPS location and/or look for requests for data or status from the medical support network 50. This system power consumption reduction can greatly enhance battery lifetime requiring less frequent battery replacement or recharging, in the case of a rechargeable battery configuration. As an alternate to using a management system to maintain a patient location data based on patient's device periodic check-in each GCMS system for each patient could have a specific time slot (for example, 30 seconds) non-overlapping with other GCMS systems to power up, acquire location coordinates from the GPS system and be alert for a call from the medical support network 50. Periodically (for example, once per week), the medical support network 50 would reset/recalibrate the system clock in system controller 24 from the atomic clock in the GPS satellite system. This would ensure that no specific GCMS system

clock would drift out of range of its allotted time slot and be unavailable for reception or drift into an adjacent time slot. Other time dividing schemes used in other arts may also be employed to maximize battery life for any system.

Turning to the second variation of the invention illustrated in Figures 3-5, it should be noted that the system of Figure 1 may also be used in the home or in the hospital using the cellular communications link card 66. However, the modified patient communications control device 20' of Figure 3 is preferably implemented with the voice and data communications network interface 28 having the capability of directly linking with a hard-wired phone line 32 or other communication services, which may include a hospital installed network, e.g. a personal computer interface to a local area network. In either case, the modified patient communications control device 20' may be implemented in a number of portable or stationary monitor 30 forms.

In the embodiment illustrated in Figure 4, all of the Figure 3 components of the modified patient communications control device 20' are located in the monitor 30. The patient link 26 and the implant wireless interface 22 are hard-wired by voice and data buses 36, 38 and 42 to the system controller 24. In the embodiment of Figure 5, the patient link 26 and the implant wireless interface 22 are located in the patient-worn communications device 40. The remaining components of the modified patient communications control device 20' are located in monitor 30, and suitable RF telemetry transceiver links are substituted for the buses 36, 38 and 42. In either embodiment, the power supply 74 of the monitor 30 may be line powered. The modified patient communications control device 20' within monitor 30 may also be coupled to a wall jack for hard-wired communications through the phone line 32 or other communications service 34 with a medical support network 50 located remotely or within the hospital.

As described above, implantable devices such as 12... 14 include telemetry transceivers with range suitable for communicating over a short range to the implant wireless interface 22 of the modified patient communications control device 20' within stand alone monitor 30. This remote link offers advantages over patient-worn electrodes or programming heads required in the standard skin contact telemetry and

monitoring used at present. Skin contact is difficult to maintain, as the adhesive for the electrodes or heads fails in time, skin irritation is often a problem and inadvertent removal of electrodes is also prevalent. Moreover, the EGM and other body condition monitoring capabilities of advanced implanted medical devices can be taken advantage of to substitute for in-hospital monitoring, e.g. Holter monitoring of the patient's electrogram. The electrogram and/or other sensor derived data, e.g. pressure, temperature, blood gases or the like, stored by the implanted device can be transmitted out continuously or on periodic automatic telemetry command and sent by the communications link to the remote or hospital medical support network 50.

In either environment of Figure 4 or 5, the patient 10 may communicate with the medical support staff at the medical support network 50 through the voice channel provided in the patient link 26. The patient communications control device 20 or 20' in either embodiment can retrieve all implanted device stored patient and device operating data on receipt of a command from the medical support network 50, process and temporarily store such data, and transmit it back to the support network 50 for analysis. Moreover, implanted devices 12...14 may be reprogrammed from the medical support network 50 to alter device operating modes and parameters employing the modified patient communications control device 20' as a programmer. Finally, the modified patient communications control device 20' can transmit an alarm to the medical support network should there be problems with the patient or implanted devices 12, 14. For example, the implanted devices 12, 14 may signal a low battery condition or a low drug supply in the case of an implanted drug dispenser or other problems found in self-diagnostic routines periodically conducted within the implanted devices 12...14.

The variations and embodiments of the GCMS of the present invention provides comprehensive monitoring of implanted medical devices independent of the geographic mobility of the patient using the devices, obviating the need for the patient to return to a designated follow-up monitoring site or clinic. Moreover, it allows determination of the patient's geographic location via the GSS 62 while providing simultaneous two-way communication with devices and the patient when desired.

in said patient communications control device, transmitting a reprogramming command to said implanted device telemetry transceiver.

20. The process of claim 15 including the step:

in the absence of an emergency patient condition, periodically reporting the
5 location of the patient to the medical network.

21. Apparatus for communicating patient device information to and from a medical device implanted in an ambulatory patient and with a remote medical support network comprising:

an implanted device telemetry transceiver within the implanted medical device
10 for communicating data and operating instructions to and from the medical device in a coded communication, the implanted device telemetry transceiver having a transceiving range extending outside the patient's body a predetermined distance sufficient to receive and transmit coded telemetry communications at a distance from the patient's body; and

15 an external patient communications control device adapted to be located in relation to the patient within the device transceiving range for communicating between the implanted medical device and a medical support network comprising means for responding to an emergency condition of the patient further comprising:

means for providing positioning data identifying the global position of
20 the patient to the patient communications control device; and

means for transmitting an encoded communication indicating an emergency condition and the global position of the patient from the patient communications control device to the medical support network.

22. The apparatus of Claim 21 wherein said external patient

25 communications device is adapted to be located in relation to the patient within the device transceiving range and further comprises communications interface means for effecting two-way communication of voice and/or data between the remote medical support network and the patient communications device and implanted device telemetry transceiver.

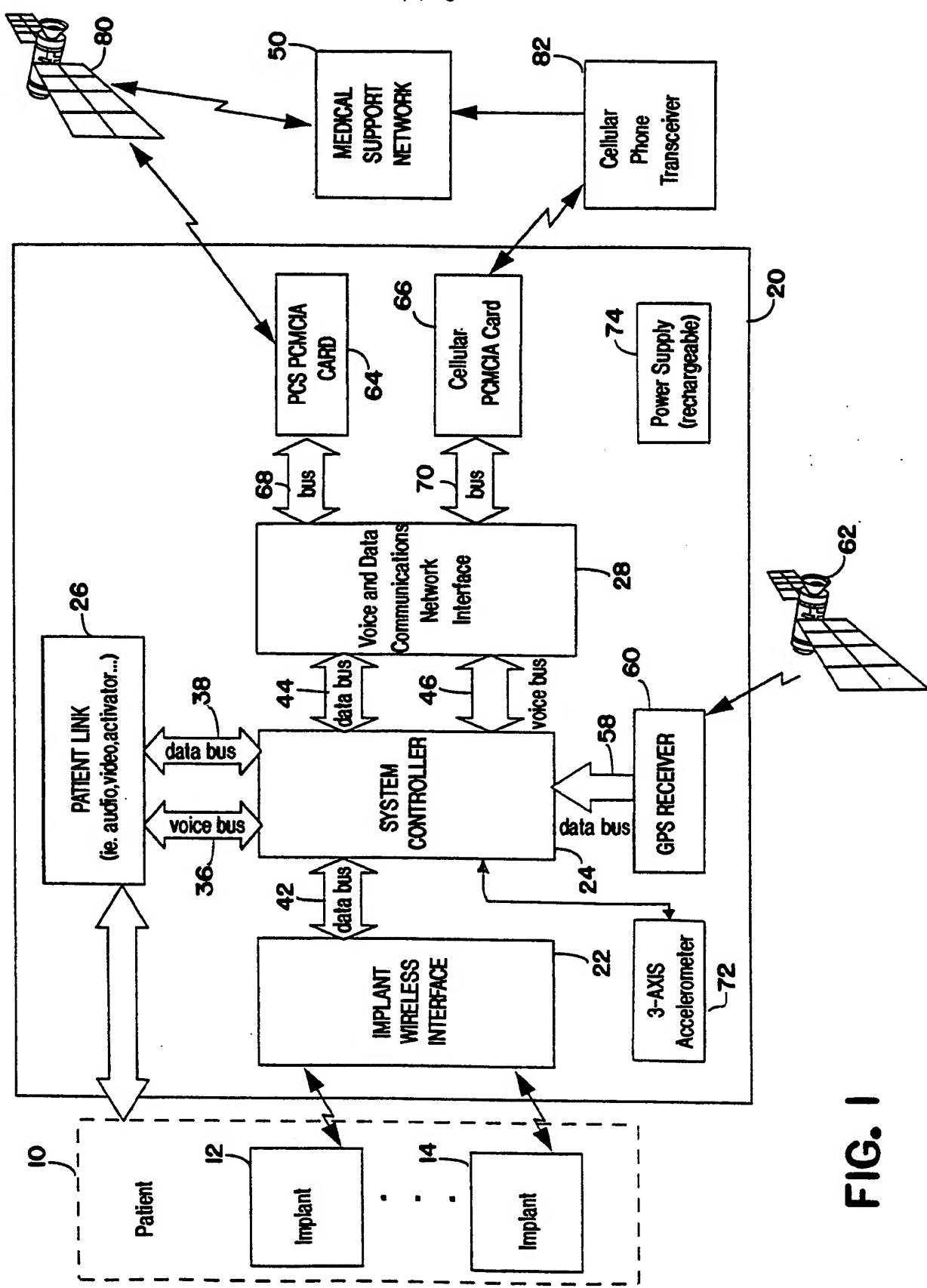
23. A system for communicating patient device information to and from a medical device implanted in an ambulatory patient and with a remote medical support network comprising:

an implanted device telemetry transceiver within the implanted medical device for communicating data and operating instructions to and from the medical device in a coded communication, the implanted device telemetry transceiver having a transceiving range extending outside the patient's body a predetermined distance sufficient to receive and transmit coded telemetry communications at a distance from the patient's body; and

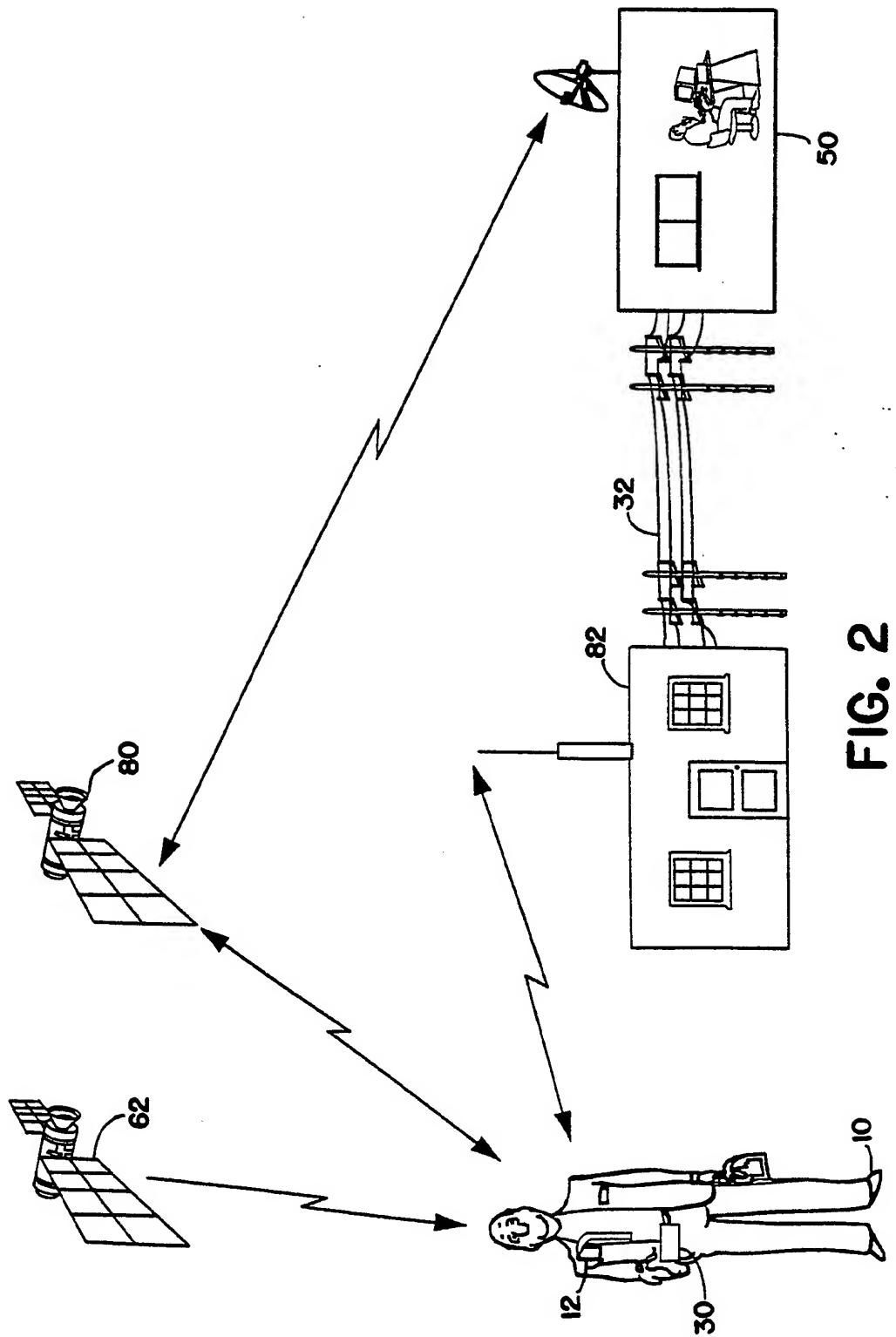
providing an external patient communications device adapted to be located in relation to the patient within the device transceiving range for communicating between the implanted medical device and a communication system,

a medical support network in communicative connection through said communications system with said implanted medical device.

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**FIG. I**

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**FIG. 2**

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 96/10325

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
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